REMARKS

A. Summary

In the Office Action under reply, the first action on the merits concerning applicants' RCE submission filed on August 27, 2009, claims 1-4, 6-8, 12, 13, 26, 29, 46, and 101-109 have been examined, with remaining claims 9-11 and 14-22 withdrawn as directed to a nonelected species and claim 76 withdrawn as directed to a nonelected invention. (Applicants note that on the Office Action summary, claims 12 and 13 were omitted from box 6, although they were examined and are included in rejections, as noted herein.)

With this response, claims 1, 3, 104, and 109 have been amended, and claim 103 has been canceled. Accordingly, upon entry of this amendment, claims 1-4, 6-22, 26, 29, 46, 47, 76, 101, 102, and 104-109 will remain pending.

The claims stand rejected as follows:

(1) Under 35 U.S.C. §112, second paragraph, as indefinite (claims 1-4, 6-8, 12, 13, 26, 29, 46, 47, and 101-108);

(2) Under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,528,125 to Alderman et al. ("Alderman"), previously cited in view of Lin et al. (Journal of Controlled Release 2001) ("Lin") and U.S. Patent Publication 2002/0054917 to Gohlke ("Gohlke") (claims 1-4, 6-8, 12, 13, 26, 46, 47, and 102-109);

(3) Under 35 U.S.C. §103(a) as obvious over Alderman in view of Lin, Gohlke, and Ventouras (claims 29 and 101); and

(4) Under 35 U.S.C. §103(a) under the judicially created doctrine of obviousness-type double patenting over claims 1-7, 10-16, and 23 of U.S. Serial No. 11/904,420.

With the exception of (4) the double patenting rejection, all other grounds for rejection are new.

Applicants acknowledge with appreciation the withdrawal of the previous art rejections, i.e., the rejection over Alderman and the rejection over Alderman in light of Ventouras.

Reconsideration is respectfully requested in light of the above amendments and the following remarks. For the Examiner's convenience, Applicants' remarks are presented in the same order in which they were raised in the Office Action.

B. March 16, 2010 Interview Summary

Applicants wish to thank Examiner Roberts for taking the time to meet with the original attorney of record, Dianne Reed, and an inventor on this application, Dr. Jerry Gin, on March 16, 2010. All issues set forth in the Office Action under reply were discussed, including the indefiniteness rejection, the art rejections, and the double patenting issues. In addition, Dr. Gin brought samples of his company's commercially available product embodying the present invention and a sample of the crisp, dry material that resulted using the Alderman technique as described in Example 1 of that patent.

This response is submitted pursuant to that discussion.

C. Amendments

Claim 1 has been amended in three respects:

- first, to specify that the micronized ethylcellulose has a mean particle size of less than 75 microns;
- second, to clarify that the weight percentage of each component is relative to the lozenge; and
- third, to specify that the flavoring agent is released over an extended time period in the range of about 15 minutes to about 4 hours.

Support for the first amendment may be found in paragraph [00037] and in previously pending claim 103 (which has now been canceled), where the "micronized" polymer is specified as having a mean particle size of less than 75 microns.

Support for the second amendment, regarding weight percentage, may be found in the specification at paragraph [00034] of the application as file.

Support for the third amendment, regarding release over a time period in the range of about 15 minutes to about 4 hours, may be found in the specification at paragraphs [0007], [0008], [00030], and [00097].

Claim 109 has also been amended to specify that the weight percent of each component is relative to the lozenge.

Claim 3 has been amended to correct antecedent basis with respect to the range of time periods given.

As indicated, support for the amendments is found in the originally filed claims and throughout the Specification, including as indicated. No new matter is added. Entry of the amendments is respectfully requested.

With respect to claim amendments, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and have not acquiesced to any rejections or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution on any presently excluded subject matter in one or more future continuation and/or divisional application(s).

D. Claim Rejections – 35 U.S.C. §112, Indefiniteness

Claims 1-4, 6-8, 12, 13, 26, 29, 46, 47, and 101-108 were rejected under 35 U.S.C. §112, second paragraph, as indefinite, on the ground that the percent values recited in the claims are incomplete because no frame of reference is specified. The rejection is now moot in light of applicants' amendment of claims 1 and 109, in which the weight percentages are now specified as being relative to the lozenge.

Note that in paragraph [00033] of the application as filed, it is stated that "typically, in a lozenge, the hydrophilic polymer and the flavoring agent each represents approximately 25-49.5 wt. % of the lozenge."

E. Claim Rejections – 35 U.S.C. §102/103

Claims 1-4, 6-8, 12, 13, 26, 46, 47 and 102-109 stand rejected under 35 USC 102(b) as being anticipated by, or in the alternative being obvious under 35 USC 103(a) over Alderman *et al.* (US 4,528,125) in view of Lin *et al.* (J. Controlled Release 2001) and Gohlke (US 2002/0054917)

Claims 1-4, 6-8, 12, 13, 26, 46, 47, and 102-109 stand rejected under 35 U.S.C. §103(a) as obvious over Alderman in view of Lin and Gohlke, the latter two references being newly cited, with Alderman previously of record as noted above. In making this rejection, the Office Action notes that Alderman purports to describe a sustained release composition that contains ethyl cellulose and a flavoring, which may be peppermint oil, with the flavoring agent representing 0.1 to 200 percent relative to the cellulose ether. It is noted in the Action that the reference does not disclose a lozenge having a soft, pliable consistency, a key feature of

applicants' claimed dosage form and the process by which it is made (as set forth in the specification and in claim 109).

The secondary references, Lin and Gohlke, are cited as pertaining to ethylcellulose particle size and chewable lozenges, respectively. More specifically, Lin is cited as describing the effect of particle size on the lag time in a delayed release/rapid release dosage form, and Gohlke et al. is cited as describing a transmucosal delivery system for administering lactoferrin and beta-glucan using a chewable lozenge that lasts from 30 seconds to 10 minutes.

The rejection is respectfully traversed.

Alderman, as applicants have stated previously, is primarily directed to a method for making a particulate or film composition using a process that involves: (1) preparing an aqueous dispersion of (a) polymer, (b) fragrance or flavor, and (c) a suspending agent that facilitates dispersion; (2) heating the dispersion to facilitate diffusion of the organic flavor or fragrance from the aqueous vehicle into the polymer particles; and (3) spraying, dewatering, or otherwise forming a dry final product from the mixture. See column 6, lines 1-53. Alderman states that the suspending agent is optional and may be omitted with smaller particles and/or high viscosity dispersions (column 2, lines 52-59).

The section of Alderman relied by the Office vis-à-vis lozenges is in column 6, lines 51-54 of the patent. Specifically, the Action indicates that the aforementioned section states that the "compositions may be formulated into lozenges." In fact, that section pertains specifically to lozenge coatings, not matrices:

> "In addition," the dispersions of this invention may be formed into ***flavored coatings*** for drugs, vitamins, capsules, gums, candies, lozenges, and the like."

(Emphasis added)

The earlier part of that paragraph, likewise, does not describe a method that would result in applicants' claimed lozenges. Rather, the description pertains to a dewatering method that is stated to result in dried particles, and to preparation of a flavored tablet using a compression technique. As discussed in the interview, the present invention is a sustained release tablet having a soft, pliable consistency; dried particles formed into a dispersion result in the crisp material shown to the Examiner and described in the previously submitted declaration, while compression would harden applicants' composition and destroy the sustained release profile set forth in the claims.

As discussed in the interview, the "closest" description in Alderman is probably that in column 6, lines 27-29, where it is stated that "cellulose ether particles may be coalesced using methods known in the art to form films or other articles having sustained release properties." In terms of "other articles," however, there is no method described or suggested in the Alderman patent for making a matrix as claimed, which provides sustained release throughout a period during which an individual usually retains a lozenge in the mouth — not days, as set forth in Alderman's examples (2-6 days in Alderman's Example 1, and 3 days in Alderman's Example 2). No method was known for making a matrix as claimed by applicants until this invention was made.

Turning now to the secondary references, Lin, first of all, pertains to the effect of particle size on the lag time in a delayed release/rapid release dosage form, i.e., a dosage form wherein a lag time prior to release is desired, and wherein when release occurs it is rapid rather than sustained. Applicants' claims, by contrast, are drawn to a sustained release matrix lozenge wherein release is gradual throughout an extended time period. (*See* claim 1: "... gradually erodes in the mouth while simultaneously gradually releasing the flavoring agent over an extended time period of in the range of about 15 minutes to about 4 hours.") The particle size specified in applicants' claims, now recited in claim 1, is relevant only in the present context, i.e., in the context of the essential oil/ethylcellulose soft matrix lozenge. Furthermore, it is axiomatic that one would not turn to a reference on unrelated dosage forms (delayed, rapid release dosage forms) for guidance on ethylcellulose particle size in an entirely different context.

The other secondary reference in this ground of rejection, Gohlke, was cited as disclosing soft lozenges for sustained release of incorporated active agents, specifically lactoferrin and beta-glucan. The majority of the reference is irrelevant, however, insofar as the emphasis is on oral administration and chewable lozenges; the presently claimed lozenge is not for oral administration (it erodes in the mouth, as indicated in claim 1), and is not intended to be chewed or have a chewable consistency (which would negate the purpose of gradual erosion, sustained release). These distinctions are reflected in the contrast between the time period for release specified in the pending claims (about 15 minutes to about 4 hours) and the time period specified in Gohlke. That is, paragraph [0056] of Gohlke states that "[t]he lozenge can be chewed for about 30 seconds to about ten minutes to maximize absorption of the active ingredients through the lining of the oral cavity and their absorption into the blood and lymphatic system." In terms

of components, Gohlke mentions the possibility of including lemon flavoring, but the lozenge is mostly composed of fillers, such as mannitol. Lozenge hardness is reported to be 25-28 kP, and are also manufactured in a tablet press, and thus compacted. A simple admixture of essential oil and micronized ethylcellulose results in a far softer composition, as demonstrated to the Examiner in the March 16 interview.

Withdrawal of this ground for rejection is respectfully requested.

F. Claim Rejections – 35 U.S.C. §103

Claims 29 and 101 stand rejected under 35 USC 103(a) as being obvious under 35 USC 103(a) over Alderman *et al.* (US 4,528,125) in view of Lin *et al.* (J. Controlled Release 2001) and Gohlke (US 2002/0054917) and further in view of Ventouras (US 6,183,775)

Claims 29 and 101, which set forth a Markush group of possible sweeteners to be incorporated into the claimed composition, stand separately rejected over Alderman, Lin, and Gohlke, as above, in further view of Ventouras. Ventouras has been cited as describing a controlled release lozenge that can contain xylitol, mannitol, and sorbitol. Ventouras is not otherwise relevant as discussed in the March 16th interview, and cannot independently support a rejection of these claims, which are patentable over Alderman, Lin, and Gohlke for the reasons discussed above.

Withdrawal of this ground for rejection is respectfully requested.

G. Obviousness-type Double Patenting

Claims 1-4, 6-8, 12, 13, 26, 29 and 101-109 stand provisionally rejected over claims 1-7, 10-16 and 23 of copending US Application No. 11/904,420.

The obviousness-type double patenting rejection over applicants' U.S. Serial No. 11/904,420 is moot as that application was abandoned as of May 24, 2010.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

The Commissioner is hereby authorized to charge any underpayments or credit any over payments in connection with this communication, including any fees for extension of time, which may be required, to Deposit Account No. 50-5132, referencing Attorney Docket No. NUV-00120US. However, an issue fee may not be charged to this account. The Examiner is invited to call the undersigned if such action might expedite the prosecution of this application.

Respectfully submitted,

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